UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NOVARTIS INTERNATIONAL PHARMACEUTICAL AG, Plaintiff, v. INCYTE CORPORATION, Defendant.	**Case No. _____** **Judge _____** **Jury Trial Demanded**

COMPLAINT

Plaintiff Novartis International Pharmaceutical AG (formerly known as Novartis International Pharmaceutical Ltd.) ("Novartis"), through undersigned counsel, states and alleges as follows based on personal knowledge as to itself and on information and belief as to all other matters:

PRELIMINARY STATEMENT

1. By this action, Novartis seeks monetary damages and a declaratory judgment relating to the application of unambiguous royalty terms in the Collaboration and License Agreement dated November 24, 2009 (the "Agreement") between Novartis and Defendant Incyte Corporation ("Incyte"). Before the Agreement was entered into, Incyte did not sell or market any pharmaceutical products in the United States, and only had several compounds in various stages of development, mostly in the areas of oncology and inflammation. Incyte recognized at that time that it could not effectively develop and ultimately commercialize these compounds on its own. Entering into the Agreement with Novartis thus allowed Incyte to not only benefit from Novartis' significant and global expertise and know-how, but also to receive hundreds of millions of dollars from Novartis in up-front and milestone payments to fund research and development activities

relating to certain compounds (the "Compounds") and to develop and commercialize clinically important pharmaceutical products (each a "Licensed Product" and altogether the "Licensed Products"). The parties also agreed to collaborate and share expertise, intellectual property, and decision-making with respect to the development and commercialization of each Licensed Product. Taking advantage of its relationship with Novartis, and commercializing a Licensed Product—ruxolitinib, a kinase inhibitor sold in the U.S. as Jakafi® ("Jakafi")—Incyte has gone from approximately $9.27 million in revenues in 2009 to approximately $1.89 ***billion*** in revenues in 2018 (equating to over a 200-time increase). Incyte's revenues are also expected to continue to increase significantly over the years, based on both its own forecasting as well as that of reputable analysts. Despite all this growth and its substantial profits, Incyte is now seeking to rewrite the parties' bargain and is refusing to pay multi-million-dollar royalties to Novartis that it owes under the express terms of the Agreement.

2. Under the Agreement, Novartis holds the rights to develop and commercialize any Licensed Products containing the Compounds outside the U.S. and Incyte holds the rights to market and sell products containing those same Compounds within the U.S. Each party pays royalties to the other on a quarterly basis based on defined percentages of annual sales of Licensed Products in its respective territory. Accordingly, Incyte must pay royalties to Novartis on a quarterly basis depending on product sales in the U.S.

3. Ruxolitinib is sold as Jakafi by Incyte in the U.S. and is sold by Novartis as Jakavi® ("Jakavi") outside the U.S. Ruxolitinib has been highly successful in treating several medical conditions, including the three medical conditions for which Jakafi has been indicated for treatment in certain patient populations in the U.S., discussed further below. For years, and through 2018, Incyte has consistently paid agreed-upon royalties to Novartis based on U.S. sales

of the Licensed Product, Jakafi. Since 2017, sales of Jakafi in the U.S. for which Incyte pays a percentage of royalties to Novartis have exceeded well over a billion dollars annually. For its part, Novartis has consistently paid Incyte royalties based on sales of the Licensed Product, Jakavi, outside of the U.S., and continues to do so consistent with the terms of the parties' Agreement.

4. Per the U.S. Food and Drug Administration ("FDA"), Jakafi is indicated for the treatment of three medical conditions in certain patient populations: (1) intermediate or high-risk myelofibrosis; (2) polycythemia vera; and (3) steroid-refractory acute graft-versus-host disease. In the U.S., Jakafi is covered by a variety of patents, as well as by orphan drug exclusivity ("ODE") under the Orphan Drug Act for two of its indications and New Clinical Investigation ("NCI") drug exclusivity for its most recent indication. Patent coverage will continue until at least June 12, 2028, and regulatory exclusivity will continue until at least May 24, 2022.

5. Pursuant to Section 8.3(c) of the Agreement, Incyte must pay Novartis based on royalty rates, on a product-by-product and country-by-country basis, for the longest possible period measured to three end-points: (a) the "last to expire of any Valid Claim of Licensed Patent Rights Covering such Licensed Product in such country"; (b) "the expiration of Regulatory Exclusivity for such Licensed Product in such country"; ***or*** (c) "ten (10) years following the date of First Commercial Sale in such country." Section 8.3(c) provides for a 50% reduction in the amount of royalties otherwise owed (the "Step Down" provision) in only two limited circumstances: (1) if there is ***no*** "Valid Claim of Licensed Patent Rights," ***and*** the product is ***not*** subject to "Regulatory Exclusivity," ***or*** (2) if the product is subject to Generic Competition (as that term is defined at Section 1.40 of the Agreement). However, in May of 2019, without any prior notice, Incyte unilaterally and improperly invoked Section 8.3(c) to reduce its royalty payments to Novartis by 50% through 2021 (after which Incyte contends royalty payments are to halt entirely).

6. Neither of these two contingencies that permit a 50% reduction in royalty payments has occurred. Incyte cannot possibly dispute that (1) Jakafi is covered by eight patents and is subject to two ODE and one NCI drug exclusivities and (2) there is no Generic Competition for Jakafi in the U.S. While Incyte's ODE status for one indication—the first indication, for intermediate or high-risk myelofibrosis—expired in November 2018, patent protections exist for the overall product (six of which apply to the myelofibrosis indication) and regulatory exclusivities remain valid and unaffected on two indications. Ignoring these undeniable facts, Incyte has sought to rewrite the parties' bargain, arguing that because the myelofibrosis indication is no longer subject to ODE exclusivity, the Step Down can be invoked. By blatantly misapplying the clear-cut contractual terms, Incyte has failed to pay approximately $27.5 million dollars to date. The amount owed to Novartis by this improper invocation of Section 8.3(c) will only continue to grow exponentially as Incyte's profits continue to climb significantly and it continues to improperly withhold significant portions of royalty payments each quarter.

7. Novartis thus seeks damages for Incyte's breach of Section 8.3 of the Agreement as well as a declaratory judgment that Section 8.3 of the Agreement requires Incyte to pay Novartis royalties on its annual net sales of Jakafi in the U.S. in the full amount, without any 50% reduction of royalties, for the 2019 calendar year and moving forward until either of the two contingencies for Step Down invocation have been satisfied. Incyte's position that the expiration of ODE status for the myelofibrosis indication entitles it to reduce the amount of royalties owed to Novartis for U.S. sales of Jakafi is flatly refuted by the plain language of the Agreement and should be categorically rejected.

THE PARTIES

8. Plaintiff Novartis is a Swiss limited company with its headquarters and principal place of business at Lichtstrasse 35, 4056, Basel, Switzerland. At the time the Agreement was signed, Novartis was named Novartis International Pharmaceutical Ltd., and was a limited company organized under the laws of Bermuda with an office at 131 Front Street, Hamilton, Bermuda HM 12. Novartis International Pharmaceutical Ltd. then transferred its domicile to Switzerland and concurrently changed its corporate name pursuant to a resolution dated November 3, 2016.

9. Defendant Incyte is a Delaware corporation with its headquarters and principal place of business at 1801 Augustine Cut-Off, Wilmington, Delaware 19803.

JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1332(a)(2). The amount in controversy exceeds $75,000, exclusive of interest and costs. Further, this controversy is one of sufficient immediacy and significance to justify declaratory relief pursuant to 28 U.S.C. § 2201. Specifically, an actual controversy of a justiciable nature exists between Novartis and Incyte concerning the interpretation and effect of Section 8.3(c) of the Agreement and whether Incyte can reduce royalty payment owed to Novartis by millions of dollars because the ODE status solely for Jakafi's myelofibrosis indication has expired.

11. Incyte expressly submitted to personal jurisdiction in this Court for controversies arising out of or related to the Agreement. Incyte also expressly consented to venue in this Court in the Agreement. Specifically, Incyte agreed in Section 14.2 to "submit[] to the exclusive jurisdiction of the United States District Court for the Southern District of New York . . . for the purposes of any suit, action or other proceeding arising out of the Transaction," and to "irrevocably

and unconditionally waive[] any objection to the laying of venue of any action, suit or proceeding arising out of this Agreement in [] the United States District Court for the Southern District of New York."

12. Venue is also proper pursuant to 28 U.S.C. § 1391(b)(3) because the parties expressly consented to personal jurisdiction in this Court pursuant to Section 14.2 of the Agreement.

13. This Court also has personal jurisdiction over Incyte, and venue is proper, because of Incyte's substantial business activities in this District.

FACTUAL ALLEGATIONS

A. The Agreement and Its Royalty Provisions

14. On November 24, 2009, the parties entered into the Agreement to collaborate with respect to the research, development and commercialization of certain pharmaceutical Compounds on a global scale.[1] Both parties are commercially sophisticated and were represented by counsel in negotiating and drafting the Agreement. In a multitude of respects, the Agreement allocates rights and obligations between the parties in connection with, among other things, engaging in research and development, obtaining worldwide regulatory approvals, and pursuing sales and marketing efforts. Incyte commercializes Jakafi in the U.S. for each of its three indications approved by the FDA, while Novartis commercializes its equivalent abroad under the trade name Jakavi. The Agreement provides for payments being owed from one party to the other in connection with various events relating to such commercialization, including a one-time $150 million-dollar upfront payment to be paid by Novartis (as set forth in Section 8.1), multi-million-dollar milestone payments to be paid by Novartis to Incyte (as set forth in Section 8.2), and mutual

[1] Capitalized terms defined in the Agreement are used herein.

royalty payments to be paid by one party to the other (as set forth in Section 8.3). The significant upfront and milestone payments made by Novartis to Incyte reflected just one of the contributions Novartis brought to the parties' collaboration with respect to the Compounds. Indeed, Novartis contributed (and continues to contribute), among other things, significant technical and industry expertise and knowledge, a track record of and reputation for excellence and medical advancement, and a global reach and scale of organization.

15. In significant part, Article 6 of the Agreement authorizes Novartis to "Commercialize Licensed Products . . . in the Novartis Territory", which means that Novartis can commercialize the Compounds in the entire world except for in the Incyte Territory, *i.e.*, in the U.S. and its territories and possessions. For Licensed Products sold in the Novartis Territory, Novartis must pay royalties to Incyte. Section 8.3(a) of the Agreement sets forth the royalty rates that Novartis agreed to pay Incyte based on annual "Net Sales." These royalty rates range depending on the product and the amount sold and are much higher than the royalty rates that Incyte must pay Novartis, discussed further below. "Net Sales" is expressly defined in Section 1.73 of the Agreement and is to be determined based on "usual and customary accounting methods," minus certain defined deductions.

16. While Novartis has obligations to make royalty payments to Incyte in relation to Novartis Territory sales, Incyte similarly has obligations to make royalty payments to Novartis in connection with commercialization in the Incyte Territory. Section 8.3(b) of the Agreement sets forth the royalty rates that Incyte agreed to pay Novartis based on annual Net Sales of a product (including Jakafi) in the U.S. These rates were termed the "Incyte Reverse Royalty Rates," and Incyte has—until 2019—been paying royalties to Novartis pursuant to this schedule since 2014.

17. Section 8.3(c) of the Agreement states that royalties payable thereunder shall be paid by Incyte or Novartis, as applicable, on a per-product and per-country basis from the date of First Commercial Sale until one of three contingencies, whichever results in the longest possible period of royalty payments. These three contingencies are as follows: (i) the "last to expire of any Valid Claim of Licensed Patent Rights Covering such Licensed Product in such country"; (ii) "the expiration of Regulatory Exclusivity for such Licensed Product in such country"; or (iii) "ten (10) years following the date of First Commercial Sale in such country." Because Section 8.3(c) of the Agreement was to apply to royalties owed by any party to the Agreement and with respect to all countries in the world (and therefore in countries that may not have patent rights and/or regulatory exclusivities, as may exist in the U.S.), the parties agreed to the third contingency so that the royalty term would last for an adequate amount of time (*i.e.*, ten years following the date of First Commercial Sale). This was an important component of the deal struck between the parties with respect to the royalty term in light of the differences in each country with respect to the issuance and validity of patents and the availability of regulatory exclusivities, if any.

18. Section 8.3(c) further provides for a reduction in royalty payments in certain limited circumstances inapplicable to the current circumstances with respect to Jakafi in the U.S. Specifically, Section 8.3(c) states, after defining the temporal terms of royalty payments, as follows:

> Notwithstanding the foregoing, in the event that either (A) the Royalty Term continues solely due to clause (ii) (i.e. in a specific country the Licensed Product is neither covered by a Valid Claim of Licensed Patent Rights nor is such Licensed Product subject to Regulatory Exclusivity) or (B) Generic Competition exists with respect to a Licensed Product in a country with respect to a royalty-reporting period, then the royalty rates in such country for such Licensed Product (for such royalty-reporting period, if applicable) will be reduced to fifty percent (50%) of the applicable rate in Section 8.3(a) or 8.3(b), based on the weighted average annual royalty rate in the Novartis Territory or the Incyte Territory, as the case may be, beginning on January 1st of the Calendar Year following the first Calendar Year in

which there exists a situation described in (A) or (B) of this sentence in the applicable country.

19. By its terms, Section 8.3(c)'s Step Down provision thus identifies only two circumstances when a royalty reduction may be triggered. The first, scenario "A," permits a royalty reduction in the event that the ***Licensed Product*** is "neither Covered by a Valid Claim of Licensed Patent Rights nor is such ***Licensed Product*** subject to Regulatory Exclusivity." That necessarily means that, to satisfy the criteria of scenario "A," the only reason the term of royalty payments continues at all (albeit at a reduced amount) is because the ten-year anniversary of the First Commercial Sale has not yet occurred. Under present circumstances, the criteria of scenario "A" have not been met:

- As described in further detail below, the Licensed Product at issue (Jakafi) is covered by multiple patents (and each of its indications is covered by multiple patents), and, therefore, scenario "A" is inoperative under these circumstances. The terms "Valid Claim" and "Licensed Patent Rights" are defined in Sections 1.112 and 1.67 of the Agreement, respectively. With respect to Jakafi, a "Valid Claim of Licensed Patent Rights" would include a claim of a valid patent (or patents) obtained for the product in the U.S. by Incyte. Incyte will have a "Valid Claim of Licensed Patent Rights" for Jakafi until at least June 12, 2028, when the last of its patents are due to expire.

- As described in further detail below, three regulatory exclusivities cover two of the three indications for the Licensed Product. "Regulatory Exclusivity" is defined in Section 1.101 of the Agreement as "the ability to exclude Third Parties from Commercializing a Licensed Product in a country, either through data exclusivity rights, orphan drug designation, or such other rights conferred by a Regulatory Authority in such country, other than through Patent Rights." In turn, "Commercialize" is defined at Section 1.19 as "***any*** activities directed to obtaining pricing

and/or reimbursement approvals, marketing, promoting, distributing, importing, offering to sell, and/or selling . . . . " (emphasis added). As such, Regulatory Exclusivity is the ability to exclude anyone that is ***not*** a party to the Agreement from undertaking ***any*** activities to commercialize a product for any reason and thus compete in the relevant market. Regulatory Exclusivity, as defined in the Agreement, would thus expire for Jakafi when Incyte can no longer prevent any commercialization efforts by others with respect to the Jakafi drug product in the U.S., which will continue to at least May 24, 2026.

As a result, neither of the two conditions precedent for invoking scenario "A" as a basis for a reduction in royalty payments (let alone both) are present.

20. In addition, scenario "B" in the Step Down provision permits a reduction in the event of Generic Competition. Incyte cannot dispute that there is no Generic Competition for the Licensed Product in the U.S. market, and in fact has conceded as much in its public statements, including to its shareholders. In Section 1.40 of the Agreement, Generic Competition is defined in relation to when "one or more Generic Products shall be commercially available in such country" for which royalty obligations apply, and the Generic Products shall in the aggregate have a market share of a defined percentage of the overall relevant pharmaceutical market. No Generic Competition as defined in the Agreement exists for Jakafi. Nor is it anticipated or even on the horizon in the foreseeable future.

21. The Agreement expressly provides for, in multiple sections, the development of more than one indication for the drugs to be commercialized thereunder. By way of example, Section 8.2, captioned "Milestone Payments," sets forth payments owed by Novartis after certain development or regulatory milestones, among others, and breaks those milestones down by the

number of indications received. Having expressly recognized the prospect of multiple indications, the parties never tied royalty payments generally or the Step Down specifically to indications, but rather, tied them to the Licensed Product as a whole, irrespective of the total number of indications. Thus, because the Licensed Product in the U.S. (Jakafi) is covered by Patent Rights and certain of its indications have been provided Regulatory Exclusivity by the FDA, the Step Down provision is inoperative.

22. On September 30, 2014, Section 8.3(b) the Agreement was amended to state that Incyte's obligation to pay royalties to Novartis applies to ***all*** annual Net Sales in the U.S. moving forward and without limitation, "irrespective of reimbursement and pricing approvals." This revision necessarily replaced the prior language of Section 8.3(b) of the Agreement that required Novartis to have obtained certain reimbursement and pricing approvals in order for the royalty stream to commence from Incyte to Novartis. Section 8.3(b) was never subsequently modified, nor was any other portion of Section 8.3 of the Agreement.

B. The FDA's Approval of Jakafi's NDA Submissions for Three Indications

23. Incyte received approval from the FDA for its June 3, 2011 New Drug Application ("NDA") for Jakafi's myelofibrosis indication on November 16, 2011. This indication relates to a rare form of blood cancer. As of November 16, 2011, Incyte was aware that the ODE for Jakafi with respect to the myelofibrosis indication would expire in November 2018.

24. Incyte subsequently submitted multiple supplemental NDA submissions to the FDA. Certain of these supplemental NDA submissions (each a "sNDA" and together the "sNDAs") related to new indications for Jakafi. The first such sNDA was submitted on June 5, 2014 for the polycythemia vera indication, which, like myelofibrosis, involves a rare blood cancer. Thereafter, on August 24, 2018, a sNDA was submitted for steroid-refractory acute graft-versus-

host disease, which is a condition that occurs after an allogenic tissue transplant, whereby the donor cells view the host/recipient's body as "foreign" and react accordingly by attacking the organs and/or tissue of the host. These two sNDAs for new indications were approved on December 4, 2014 and May 24, 2019, respectively, and both included seven-year ODE status. The latter also included NCI exclusivity.

C. Existence of Patents and Regulatory Exclusivities for Jakafi

25. Upon information and belief, Incyte submitted its first patent application relevant to the Compounds and Jakafi in the 2005/2006 timeframe. The patent, which was received and is numbered 7598257, was submitted to the FDA's "Orange Book Listing" on December 1, 2011, after the FDA approved the NDA for the myelofibrosis indication.

26. Jakafi is covered by eight patents, which range in expiration date from December 12, 2026 (the earliest expiration date) to June 12, 2028 (the latest expiration date). The numbers for the patents protecting Jakafi are 7598257, 8415362, 8722693, 8822481, 8829013, 9079912, 9814722, and 10016429, all of which are publicly listed on the FDA's website in its "Orange Book" listing for Jakafi.

27. Valid Claims of Licensed Patent Rights, as those terms are defined in the Agreement, will exist for Jakafi (the Licensed Product) through at least June 12, 2028.

28. Three regulatory exclusivities are also still in effect in the United States for Jakafi under codes ODE-79, ODE-238, and I-799: (a) one ODE for the polycythemia vera indication, which expires on December 4, 2021 (*i.e.*, seven (7) years after FDA approval); (b) one ODE for the steroid-refractory acute graft-versus-host disease indication, which expires on May 24, 2026 (*i.e.*, seven (7) years after FDA approval); and (c) the NCI exclusivity for the steroid-refractory

acute graft-versus-host disease indication, which expires on May 24, 2022 (*i.e.*, three (3) years after FDA approval).

29. Incyte's ODE for the myelofibrosis indication expired seven (7) years from approval of the NDA—*i.e.*, on November 16, 2018. It is the only regulatory exclusivity for Jakafi that has expired, and no other regulatory exclusivity will expire for nearly two years.

30. The longest regulatory exclusivity designation received for Jakafi is the ODE designation for steroid-refractory acute graft-versus-host disease through May 24, 2026. Regulatory Exclusivity (as that term is defined in the Agreement) will thus exist for Jakafi through at least May 24, 2026.

D. Incyte's Royalty Reports and Payments

31. It is Novartis' understanding that the First Commercial Sale of Jakafi by Incyte was in the last quarter of 2011 after the FDA approved the NDA for the first myelofibrosis indication. This would have marked the commencement of the term by which Incyte was to pay royalties to Novartis pursuant to Sections 8.3(b) and 8.3(c) of the Agreement; however, Incyte was initially permitted under Section 8.3(b)(i) to withhold payments until Novartis received certain reimbursement and pricing approvals in at least three (3) specifically-delineated countries in the European Union. The parties subsequently removed that provision in the third quarter of 2014.

32. Commencing in the second half of 2014 and through the fourth quarter of 2018, Incyte submitted quarterly royalty reports to Novartis consistent with Section 8.4 of the Agreement and then paid the corresponding royalty amounts. Each such royalty report detailed Incyte's sales of Jakafi for the quarter, reduced that amount by a defined percentage as provided in Section 1.73 of the Agreement, and then calculated the amount of royalties owed to Novartis pursuant to the

tiered royalty rate structure set forth at Section 8.3(b) of the Agreement (the "Incyte Royalty Payment Schedule").

33. Incyte's sales of Jakafi have increased dramatically since Jakafi was first approved back in late 2011. Incyte reported to the SEC $2,012,000.00, $136,001,000.00, and $235,443,000.00 in net product revenues for the 2011, 2012, and 2013 fiscal years, respectively, with Jakafi as Incyte's only FDA-approved product. Comparatively, in 2017 and 2018, Incyte reached Annual Net Sales greater than $300 million for Jakafi by the second quarter each year. Accordingly, consistent with the Incyte Royalty Payment Schedule, a 5% royalty rate was applied starting in the second quarter each such year (and continued to be applied throughout that year).

34. In 2017, Incyte's Annual Net Sales for Jakafi were over $1.1 billion for the 2017 fiscal year, resulting in royalty payments due Novartis of $50,536,212.00.

35. In 2018, Incyte's Annual Net Sales for Jakafi were nearly $1.4 billion for the 2018 fiscal year, resulting in royalty payments due Novartis of $62,961,230.00.

36. Incyte reported during its earnings call for the first quarter of 2019 that "Jakafi sales increased by 20% over Q1 of last year driven by demand in both approved indications." Novartis expects Annual Net Sales for Jakafi to continue to grow given the newly-approved third indication for the drug. Reputable analyst reporting also expects Jakafi's profits to continue to grow, with available estimates through 2022.

37. On May 1, 2019, Incyte's Finance Director and Assistant Controller sent Incyte's royalty report for the quarter ending March 31, 2019 to Novartis, reporting $375,611,113.00 in Net Sales for the quarter and a royalty payment owed of $13,404,945.00 (the "Initial Q1 2019 Royalty Amount"). Novartis issued its invoice corresponding to the Initial Q1 2019 Royalty Amount on May 6, 2019, expecting it to be paid in full.

38. On May 16, 2019, without any prior notice following the expiration of the ODE for the first indication six months earlier, Incyte suddenly sent Novartis a revised royalty report for the quarter ending March 31, 2019, notifying Novartis that it was unilaterally reducing the royalty amount by 50% and demanding either a revised invoice or a credit memo. On June 17, 2019, Incyte notified Novartis that it had paid half of the Initial Q1 2019 Royalty Amount by wire transfer.

39. On the very next day, June 18, 2019, Novartis unequivocally disputed Incyte's unilateral reduction of the royalty owed for the first quarter of 2019. Novartis explained that ODE expiration for the myelofibrosis indication did not entitle Incyte to reduce royalties owed to Novartis, whether for the first quarter of 2019 or otherwise, under the express terms of the Agreement. Novartis also flagged that the Jakafi product was still subject to full patent protections. Despite the express contract terms to the contrary, Incyte insisted that it would be reducing the royalty payments for Jakafi moving forward by email dated June 21, 2019.

40. On August 13, 2019, Incyte's Finance Director and Assistant Controller sent the company's royalty report for the quarter ending June 30, 2019 to Novartis, reporting $409,506,077.00 in Net Sales for the quarter and incorrectly reporting a royalty payment owed of $10,032,899.00. That royalty report unilaterally incorporated a 50% reduction in royalties owed to Novartis, as it contended that a royalty rate of only 2.5% of sales above $300 million was due to Novartis (*i.e.*, half of the 5% royalty rate set forth in the Incyte Royalty Payment Schedule).

41. On August 20, 2019, Novartis sent Incyte an invoicing letter (the "August 20 Invoice Letter") in connection with Incyte's August 13, 2019 royalty report for the second quarter of the year. That letter demanded that Novartis receive (a) the full 5% of royalties owed for the Net Sales of Jakafi for the second quarter of 2019, amounting to $20,065,798.00 (and thus double

of what Incyte had suggested in its August 13, 2019 royalty report), and (b) the remaining royalties still owed from the first quarter of 2019. Incyte refused to do either.

42. Incyte's royalty report for the third quarter of 2019, like the royalty report for the second quarter, unilaterally incorporated a 50% reduction in royalties owed to Novartis. The 2.5% royalty payment that Incyte reported to Novartis was $10,617,983, whereas at a 5% royalty payment rate, Novartis would be paid $21,235,966 total.

43. Prior to the myelofibrosis ODE expiration, Incyte did not send any contemporaneous notification to Novartis that said that the Step Down was coming into effect. And after the myelofibrosis ODE expiration, Incyte did not advise Novartis that the Step Down provision should now apply (as it now contends). In fact, Incyte waited over half of a year ***after*** the myelofibrosis ODE expired to take the position it is now taking.

44. Novartis relied on its commercially reasonable understanding of Section 8.3 when it agreed to the Agreement. Novartis never would have agreed to the Agreement if it understood the narrow Step Down in Section 8.3(c) to apply as Incyte now argues it should apply. Until May 2019, Incyte never conveyed, in words or substance, the position that it now apparently is advancing regarding the Step Down.

E. Compliance with the Dispute Resolution Process Set Forth in the Agreement

45. Section 13.1 of the Agreement, entitled the Dispute Resolution Process, provides that "[i]f the Parties are unable to settle such dispute within" an identified time frame "and a Party wishes to pursue the matter, the matter may be referred by either Party to the Executive Officers, who shall meet to attempt to resolve the dispute in good faith." In compliance with this provision, the parties' respective General Counsels engaged in discussions regarding the royalty dispute on

July 26, 2019. Thereafter, Novartis escalated the dispute to the Executive Officer level by correspondence dated August 21, 2019.

46. Since formally escalating the dispute to the Executive Officer level, Novartis has further conferred with Incyte on multiple occasions in good faith in an effort to resolve the parties' dispute as to the amount of royalties owed by Incyte. These discussions have involved the Executive Officers as well as the General Counsels of both parties. Incyte has clung to its misreading of the Agreement and has refused to pay the full amount of royalties owed to Novartis for the 2019 fiscal year and moving forward.

47. Section 13.1 provides: "If the Executive Officers are unable to settle the dispute within" an identified time frame "after referral thereto pursuant to Section 13.1, then each Party reserves its right to any and all remedies available under law or equity . . . ." As the period to resolve the dispute at the Executive Officer level has lapsed, Novartis has satisfied any conditions precedent to pursue damages and declaratory relief.

FIRST CAUSE OF ACTION

Breach of Contract

48. Novartis restates, realleges, and incorporates by reference each of the allegations set forth above as if fully set forth herein.

49. The Agreement constitutes an enforceable contract between two sophisticated parties and was negotiated at arms' length and with the aid of seasoned deal counsel.

50. The Agreement's Section 8.3(c) clearly spells out the terms and conditions for royalty payments, including those by Incyte to Novartis. In the Agreement, Incyte agreed to pay tiered royalty payments to Novartis in connection with its sales of Jakafi in the U.S. Incyte has failed to comply with its contractual obligations by unilaterally and improperly invoking the Step

Down provision in an effort to only pay Novartis 2.5% royalties (as opposed to 5% given how high its sales are), garnering a multi-million-dollar (and perhaps near-billion-dollar) windfall. This is a material breach of an express contractual obligation given the significant amount of money that Incyte is refusing to pay Novartis.

51. In violation of Section 8.3 of the Agreement, Incyte has improperly withheld from Novartis $27,353,353.00 in royalty payments to date, and rising.

52. As a consequence of Incyte's refusal to honor its contractual obligation to pay specific royalties, as set forth at Section 8.3(c) of the Agreement, Novartis has been and will continue to suffer damages.

53. Novartis has satisfied any conditions precedent to the recovery of unpaid royalty payments pursuant to the Agreement.

54. Novartis has not breached any of its own obligations under the Agreement, and has always faithfully and satisfactorily fulfilled all of its own contractual duties and responsibilities.

SECOND CAUSE OF ACTION

Declaratory Judgment

55. Novartis restates, realleges, and incorporates by reference each of the allegations set forth above as if fully set forth herein.

56. It is Novartis' position that Incyte must continue to pay royalties at the rates set forth in the Incyte Royalty Payment Schedule in the Agreement. For Annual Net Sales of over $300 million, as is currently the case for Jakafi in the United States, this would amount to a royalty rate of 5%; there is no basis to invoke a 50% reduction of this rate to 2.5% as Incyte contends. Incyte takes the opposite position.

57. An actual and justiciable controversy thus exists between Novartis and Incyte that is ripe for adjudication. The dispute between the parties is by no means hypothetical, but is rather very real and involves significant royalty amounts being improperly withheld by Incyte.

58. Pursuant to 28 U.S.C. § 2201 and Rule 57 of the Federal Rules of Civil Procedure, this Court is authorized to resolve this dispute and provide the declaratory relief requested, and resolution of this dispute will aid in the termination of this controversy by making clear to all interested parties that Incyte must continue to pay full royalties to Novartis consistent with the Incyte Royalty Payment Schedule, and that Novartis will receive these substantial royalty payments on a quarterly basis as the parties agreed in Sections 8.3 and 8.4 of the Agreement.

59. In the absence of the declarations sought herein, Incyte will continue to unilaterally impose significant reductions to its royalty payments to Novartis and insist that it need only pay half of the royalty rates set forth in the Incyte Royalty Payment Schedule. There is no basis to permit Incyte to continue to withhold many millions of dollars each quarter, nor is there any basis to wait until further royalty reports are issued by Incyte that incorporate unsupported and unilateral reductions in amounts owed to Novartis under the terms of the Agreement.

60. There is no other pending litigation between Novartis and Incyte with respect to royalties owed by either side under the Agreement.

61. This controversy is of sufficient immediacy, reality, and ripeness to warrant the issuance of a declaratory judgment at this time so the parties can avoid further disputes concerning the amount of royalties owed by Incyte.

PRAYER FOR RELIEF

WHEREFORE, Novartis respectfully requests that the Court enter a judgment as follows:

A. Finding that Incyte is in violation of Section 8.3(c) of the Agreement and award Novartis all missing royalty payments since Incyte improperly invoked the Step Down provision with respect to royalties owed in the first quarter of 2019 (including but not limited to the $27,353,353.00 in royalty payments already withheld for the first three quarters of 2019), as well as interest on these delayed royalty payments;

B. Declaring that Section 8.3(c) of the Agreement does not permit Incyte to reduce royalty payments otherwise owed to Novartis by 50% when one or more patents and/or regulatory exclusivities pertain to Jakafi in the U.S.;

C. Declaring that Incyte must pay the remaining 50% of royalty payments it has improperly withheld during the 2019 calendar year and thereafter;

D. Awarding costs and expenses incurred in pursuing this action, including all legal fees; and

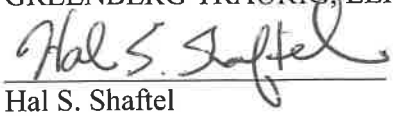
E. Granting such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Novartis demands a trial by jury on all issues so triable.

Respectfully Submitted,

GREENBERG TRAURIG, LLP



Hal S. Shaftel
Sylvia E. Simson
MetLife Building
200 Park Avenue
New York, New York 10166
Tel: (212) 801-9200
Fax: (212) 801-6400
shaftelh@gtlaw.com
simsons@gtlaw.com

Attorneys for Plaintiff Novartis International Pharmaceutical AG

Date: January 15, 2020